Pharmacy Policy

Antineoplastic Agents

Policy Number: 9.700
Version Number: 2.0
Version Effective Date: 9/1/2021

Product Applicability ☐ **All Plan[+] Products**

Well Sense Health Plan
☐ New Hampshire Medicaid

Boston Medical Center HealthNet Plan
☐ MassHealth- MCO
☐ MassHealth- ACO
☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct
☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Abiraterone acetate tablets
- Alecensa ® (alectinib capsule)
- Alunbrig™ (brigatinib tablets)
- Afinitor® (everolimus tablet)
- Afinitor Disperz® (everolimus soluble tablet)
- Bosulif® (bosutinib tablet)
- Braftovi® (encorafenib capsules)
- Cabometyx™ (cabozanitinib tablet)
- Caprelsa® (vandetanib tablet)
- Cometriq® (cabozantinib tablet)
- Erivedge® (vismodegib capsule)
- Everolimus tablet
- Farydak® (panobinostat capsule)
- Gilotrif® (afatinib tablet)
- Iclusig™ (ponatinib tablet)
- Inlyta® (axitinib tablet)
- Iressa® (gefitinib tablet)
- Kisqali® (ribociclib tablets)
- Lenvima™ (lenvatinib capsule)
- Lonsurf® (tipiracil hcl and trifluridine tablet)
- Lynparza™ (olaparib capsule, and tablets)
- Mekinist™ (trametinib tablet)
- Nexavar® (sorafenib tablet)
- Ninlaro® (ixazomib capsule)

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

- Odomzo® (sonidegib capsules)
- Pomalyst® (pomalidomide capsule)
- Revlimid® (lenalidomide capsule)
- Rubraca™ (rucaparib tablets)
- Rydapt® (midostaurin capsules)
- Sarclisa® (Isatuximab–IRFC injection)
- Sprycel® (dastinib tablet)
- Stivarga® (regorafenib tablet)
- Sutent® (sunitinib capsule)
- Sylatron™ (peginterferon Alfa-2b injection)
- Tafinlar® (dabrafenib capsule)
- Talzenna® (talazoparib capsule)
- Tasigna® (nilotinib capsule)
- Tibsovo® (ivosidenib tablet)
- Tykerb® (lapatinib tablet)
- Ukoniq (umbralisib tosylate tablet)
- Venclexta™ (venetoclax tablet)
- Verzenio™ (abemaciclib tablet)
- Votrient® (pazopanib tablet)
- Xalkori® (crizotinib capsule)
- Xatmep (methotrexate oral solution)
- Xtandi® (enzalutamide capsule)
- Zejula™ (niraparib capsules)
- Zolinza® (vorinostat capsule)
- Zydelig® (idelalisib tablets)
- Zytiga® (abiraterone acetate tablet)

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	• FDA approved indication
	• Use supported by:
	  ○ American Hospital Formulary Service Drug Information
	  ○ DRUGDEX Information System
	  ○ United States Pharmacopeia- Drug Information
	  ○ National Comprehensive Cancer Network (categories 1,2a, and 2b)
	• Medically accepted indications will also be considered for approval.

Exclusion Criteria	• Experimental or Investigational Use • Being used in a clinical trial

Required Medical Information	Documentation of the following:
	
	1. A documented diagnosis for a medically accepted indication including:
	  • Use of a drug which is FDA-approved and that the quantity being prescribed is consistent with dosing listed in manufacture package labeling; OR
	  • Use of which is supported by one or more citations included or approved for inclusion in any of the compendia:
	  ○ American Hospital Formulary Service Drug Information
	  ○ DRUGDEX Information System
	  ○ United States Pharmacopeia-Drug Information (or its successor

	publications) ○ National Comprehensive Cancer Network (categories 1, 2a, 2b only); AND 2. Documentation of dose and dates of all previous therapies and the resulting outcomes. For example, NCCN guidelines 'preferred' regimens over 'other' regimens with evidence Category 1, 2a and 2b; AND 3. Documentation that the proper succession of the therapies (as indicated in the FDA labeling or compendia) have been tried and failed (i.e. intolerance, contraindication, or progression; AND 4. Chart notes detailing the member's current clinical status; AND 5. Chart documentation and related lab work, test results, or clinical markers supporting the diagnosis and or continuing treatment.
Prescriber Restriction	Prescriber must be a specialist appropriate to the disease state being treated (e.g. oncologist, hematologist, etc…)
Coverage Duration	Initial and Re-authorization: Maximum of 12 months
Other criteria	Reauthorization: 1. The clinical condition has improved or stabilized (decreased progression) without treatment-related adverse events.

Applicable Coding:

Code	Medication
J9227	Injection, isatuximab-irfc (Sarclisa), 10 mg

Clinical Background Information and References

1. AdcetrisTM [package insert]. Bothell (WA): Seattle Genetics; March 2016.
2. ErwinazeTM [package insert]. Langhome (PA): EUSA Pharma, Inc.; Nov 2011.
3. Inlyta® [package insert]. New York (NY): Pfizer Inc.; Jan 2012.
4. Kyprolis® [package insert]. San Francisco (CA): Onyx Pharmaceuticals, Inc.; July 2012.
5. Zaltrap® [package insert]. Bridgewater (NJ): Sanofi-Aventis U.S. LLC; Aug 2012.
6. Bosulif® [package insert]. New York (NY): Pfizer Inc.; Apr 2013.
7. Stivarga® [package insert]. Wayne (NJ): Bayer HealthCare Pharmaceuticals Inc.; Feb 2013.
8. SynriboTM [package insert]. North Wales (PA): Teva Pharmaceuticals USA, Inc.; Oct 2012.
9. IclusigTM [package insert]. Cambridge (MA): ARIAD Pharmaceuticals, Inc.; Dec 2015.
10. Pomalyst® [package insert]. Summit (NJ): Celgene Corporation; Feb 2013.

11. KadcylaTM [package insert]. San Francisco (CA): Genentech, Inc.; May 2013.
12. NCCN Drugs & Biologics Compendium™ [database on the internet]. Fort Washington (PA): National Comprehensive Cancer Network; Updated periodically [cited 2014 Jun 24]. Available from http://www.nccn.org.
13. MekinistTM [package insert]. Triangle Park (NC): GlaxoSmithKline; Jan 2014.
14. Tafinlar® (package insert). Triangle Park (NC): GlaxoSmithKline; Jan 2014.
15. Folotyn® (package insert). Westminster (CO): Allos Therapeutics; Jan 2011.
16. Zelboraf® (package insert). San Francisco (CA): Genentech; Mar 2014.
17. Caprelsa® (package insert). Wilmington (DE): AstraZeneca; Mar 2014.
18. CyramzaTM (package insert). Indianapolis (IN): Eli Lilly and Company; Apr 2015.
19. SylvantTM (package insert). Horsham (PA): Janssen; Apr 2014.
20. ZykadiaTM (package insert). East Hanover (NJ): Novartis; Apr 2014.
21. Marqibo®(package insert). South San Francisco (CA): Talon; Oct 2012.
22. Lynparza™ (package insert). Wimington (DE): AstraZeneca; Dec 2014.
23. Farydak® (package insert). East Hanover (NJ): Novartis; Feb 2015.
24. Opdivo™ (package insert). Princeton (NJ): Bristol Myers Squibb; May2016.
25. Blincyto™ (package insert). Thousand Oaks (CA): Amgen; Dec 2014.
26. Keytruda® (package insert). Whitehouse (NJ): Merck; Jan 2015.
27. Beleodaq® (package insert). Irvine (CA): Spectrum Pharmaceuticals; Jul 2014.
28. Treanda® (package insert). North Wales (PA): Teva Pharmaceuticals. Mar 2015.
29. Zydelig® (package insert). Foster City (CA). Gilead. Jul 2014.
30. Lenvima™ (package insert). Woodcliff (NJ). Eisai. May 2016.
31. Alecensa (alectinib) [prescribing information]. South San Francisco, CA: Genentech USA Inc; December 2015.
32. Cabometyx (cabozantinib) [prescribing information]. South San Francisco, CA: Exelixis Inc; April 2016.
33. Empliciti (elotuzumab) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; November 2015.
34. Imlygic (talimogene laherparepvec) [prescribing information]. Thousand Oaks, CA: Amgen Inc; October 2015.
35. Lonsurf (trifluridine/tipiracil) [prescribing information]. Princeton, NJ: Taiho Oncology; September 2015.
36. Ninlaro (ixazomib) [prescribing information]. Cambridge, MA: Takeda Pharmaceutical Company Limited; November 2015.
37. Onivyde (irinotecan [liposomal]) [prescribing information]. Cambridge, MA: Merrimack Pharmaceuticals; October 2015.

38. Valchlor (mechlorethamine) [prescribing information]. South San Francisco, CA: Actelion Pharmaceuticals; August 2015.

39. Venclexta (venetoclax) [prescribing information]. North Chicago, IL: AbbVie Inc.; April 2016.

40. Yondelis (trabectedin) [prescribing information]. Horsham, PA: Janssen Products; November 2015.

41. Sarclisa® (Isatuximab–IRFC injection) MG) [prescribing information]. Bridgewater, NJ: Sanofi-aventis US LLC; March 2021.

42. Ukoniq (Umbralisib Tosylate Tab 200 MG) [prescribing information]. Edison, NJ: TG Therapeutics Inc; February 2021.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee, NH DHHS

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.041 Antineoplastic Agents Policy retired, new policy created	1/1/2021	P&T Committee
5/13/2021	Removed Ibrance, Imbruvica, Jakafi and Tagrisso from this policy and created drug specific policies for each. Addition of new drugs Sarclisa® (Isatuximab–IRFC injection) and Ukoniq (Umbralisib Tosylate Tab 200 MG) to the policy.	9/1/2021	P&T Committee

Next Review Date

5/2022

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.